

REMARKS

Following entry of the above amendment, claims 25 and 29 to 44 will be pending in this application. Claims 1 to 24 and 26 to 28 were canceled in a previous amendment. Claims 29 to 44 are added in this amendment. Support for the amendment to claim 25 and new claims 35 to 39 can be found, *e.g.*, in the specification at page 16, lines 18 to 29. Support for new claim 30 can be found, *e.g.*, in the specification at page 8, lines 18 to 22, and at page 16, line 30, to page 17, line 10. Support for new claim 31 can be found, *e.g.*, in the specification at page 9, line 10. Support for new claims 32 to 34 can be found, *e.g.*, in the specification at page 6, lines 16 to 33, and page 9, lines 18 to 23. No new matter has been added.

Specification

The amendments to the specification update the cross-reference to related applications to reflect the issuance of U.S. Applications No. 09/839,479 and 09/418,710, as U.S. Patents No. 6,727,222 and 6,596,482, respectively.

The specification was objected to for containing embedded hyperlinks and/or other forms of browser-executable code. The specification has been amended to remove the embedded hyperlinks. Applicant submits that this obviates the objection.

The specification was further objected to for allegedly not reciting sequence identifiers in the description of FIGs. 6A, 6B, 10, and 13-18. Applicant respectfully points out that the specification was amended to include the appropriate sequence identifiers in the amendment of November 5, 2003. Applicant requests reconsideration and withdrawal of this objection.

Rejection under Section 101

Claim 25 was rejected under section 101 for allegedly being directed to non-statutory subject matter. In accordance with the Examiner's helpful suggestion at the top of page 3 of the Office Action, applicant has limited the antibody of claim 25 to a "substantially pure" antibody. As indicated by the Examiner, this limitation clearly distinguishes the claimed antibody from a naturally occurring antibody (assuming any antibodies meeting the other criteria of the claim

indeed exist naturally, a situation that applicant doubts is true). Accordingly, applicant requests reconsideration and withdrawal of the rejection.

Rejection under Section 112, second paragraph

Claim 25 was rejected under section 112, second paragraph, as allegedly being indefinite for the recitation of the term "gene." Applicant has amended claim 25 to remove this term, and submits that this amendment obviates the rejection.

Rejection under Section 112, first paragraph

Claim 25 was rejected under section 112, first paragraph, as allegedly not providing written description or enablement for any antibody that binds to a polypeptide consisting of an amino acid sequence 60% identical to any of SEQ ID NOs: 1, 13, 21, 27, or 29. To the extent the rejection may be applied to any of the claims as presently amended, applicants respectfully traverse.

Applicant has amended claim 25 to recite that the polypeptide to which the antibody binds is 95% identical to any one of SEQ ID NOs: 1, 13, 21, 27, or 29 and has also added new claims 29 to 44. These amended and new claims are analogous to those granted in U.S. Patent No. 6,272,222, the parent of this divisional application. Applicant maintains that the amended claims comply with the written description and enablement requirements of section 112, first paragraph.

Noelle v. Lederman, 355 F.3d 1343, 69 USPQ2d 1508 (Fed. Cir. 2004), holds that:

[A]s long as an applicant has disclosed a "fully characterized antigen," either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen.

Applicant submits that the antigens recited in the claims, *i.e.*,

a polypeptide consisting of an amino acid sequence at least 95% identical to any one of SEQ ID NOs: 1, 13, 21, 27, or 29, wherein the polypeptide functions as a transcriptional regulator and comprises a bromodomain (claim 25);

a polypeptide consisting of the amino acid sequence of any one of SEQ ID NOs: 1, 13, 21, 27, or 29 (claim 29);

a polypeptide consisting of the amino acid sequence of any one of SEQ ID NOs: 1, 13, 21, 27, or 29, with up to 30 conservative amino acid substitutions, wherein the polypeptide regulates transcription of a gene and comprises a bromodomain (claim 30); and

a polypeptide encoded by a nucleic acid that hybridizes under high stringency conditions (65 °C, 2x SSC) to a nucleotide sequence consisting of the complement of the coding sequence of any one of SEQ ID NOs: 2, 14, 22, 28, or 30, wherein the polypeptide regulates transcription of a gene and comprises a bromodomain (claim 31),

are fully characterized antigens meeting both the written description and enablement requirements, as evidenced by the grant of a patent directed to polypeptides of similar or broader scope (*cf.* U.S. Patent No. 6,272,222). Therefore, based on the reasoning of *Noelle*, the present claims are both sufficiently described and fully enabled.

Further, the question to be asked is not the one presented by the Examiner, *i.e.*, whether an antibody directed to a polypeptide of 60% (or 95% or whatever) identity to SEQ ID NO:1, 13, 21, 27, or 29 *could also bind to SEQ ID NO:1, 13, 21, 27, or 29*. The claimed antibody need only bind to the polypeptide described in the claim in order to meet the criteria of the claim. Such an antibody meets the written description requirement (because the application describes it) and the enablement requirement (because one of ordinary skill would know perfectly well how to make and use it: simply immunize an animal with an immunogen that is the polypeptide having the specified degree of identity (95% or whatever) to SEQ ID NO:1, 13, 21, 27 or 29, using standard methods; purify the antibody by standard means; and use the antibody for isolating or assaying a polypeptide with the specified degree of identity to SEQ ID NO:1, 13, 21, 27 or 29, *i.e.*, the same polypeptide as that used to raise the antibody). Applicant does not understand why the examiner believes the claimed antibody must be able to bind to SEQ ID NO:1, 13, 21, 27 or 29 as well as to the polypeptide that was used as the immunogen. The claim does not require it.

Applicant respectfully submits that the present claims are in condition for allowance and requests confirmation of such from the Examiner.

Applicant : Michael H. Jones
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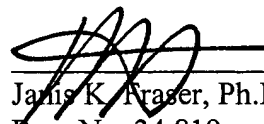
Attorney's Docket No.: 14875-042004 / C2-901DP1PCT-USD3

Enclosed is Petition for Extension of Time along with the required fee. Please apply any other charges or credits to deposit account 06-1050, referencing Attorney Docket No. 14875-042004.

Respectfully submitted,

Date: _____

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